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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,288	01/14/2004	Yaron Keidar	BIO-173-CIP	4500
27777 7590 01/18/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/757,288

Applicant(s)

KEIDAR, YARON

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25 and 27-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 27-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2006 has been entered.

In particular, it is noted that applicant's amendments have obviated the 35 USC 101 and 35 USC 112 rejections.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 25, 27, 28 and 30-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman, III et al (6,575,969) in view of the teaching of Ben-Haim et al (6,690,963).

Rittman, III et al disclose a system and method for ablating and imaging tissue. With regard to the apparatus (applicant's claims 25-48), the Rittman system includes a probe (Figure 1) which is adapted to be inserted into tissue. The probe itself may act as a sensor and used in conjunction with CT, MR, ultrasound and acoustic imaging to measure one or more local parameters and provide an image of the probe within the tissue. Additionally, the probe may be provide with thermal sensors for sensing local parameters in tissue (see Abstract and col. 12, lines 12-43). Rittman discloses an

ablative device for providing a set dosage of energy, a display to show a map of the tissue being treated and a controller for generating images including predicted and actual ablation profiles (see Figure 6 and column 14). In particular, column 14, lines 9+ discusses that the image data may be fed into the computer system and used to represent the system in various ways, including displaying calculated outcomes based on tissue and energy levels for preplanning the settings as well as overlaid models to show the comparative pre-planned view with the actual ablated tissue image. The computer controls the delivery of energy based on input parameters such as temperature and image data (see col. 13). It is noted that applicant's apparatus claims are replete with recitation of elements "adapted" to perform various functions. The examiner maintains that the imaging and control system disclosed by Rittman is inherently capable of (i.e. "adapted to") performing the functions. Additionally Rittman specifically disclose the performance of these various functions, including providing a mapping imaging prior to ablation, providing an image of a predicted extent of the ablation profile, and providing an image of the actual ablation profile in comparison with the predicted profile image (col. 14). The only feature not expressly disclosed by Rittman, III et al is a position sensor for generating signals to determine the position and orientation of the probe during use.

Ben-Haim et al disclose a system for determining the location and orientation of a probe within the body, much like the Rittman et al system. In particular, Ben-Haim et al teach that the probe may be provided with sensor coils (Figure 2) to assist in determining the location and orientation of the device during imaging. The examiner

maintains that one of ordinary skill in the art would recognize that any known alternative location means, such as taught by Ben-Haim et al, may be used when identifying the location of a medical probe. Use of that information to determine the predicted profiles in the Rittman, III et al system would be an obvious, if not inherent, use of the information.

To have provided the Rittman, III et al system with sensor coils on the probe device to provide information regarding the location and orientation of the device within tissue during imaging would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Ben-Haim et al.

Claims 25, 27-40 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (2003/0109871) in view of the teachings of Rittman, III et al (6,575,969) and Ben Haim et al (6,690,963).

Johnson et al disclose a system and method for treating tissue comprising a probe (12) that is brought into contact with tissue, the probe having sensors for measuring one or more local parameters (e.g. impedance) of tissue in order to display a map of the tissue. Paragraph [0102] of the Johnson et al device addresses the use of mapping to show pre and post-surgical mapping of tissue during an ablation procedure using the sensors. Further, paragraph [0100] discloses the use of the sensors and mapping to control the delivery of ablation energy. Johnson et al fully disclose all the necessary display and control means for viewing, mapping and controlling the delivery of energy during the procedure. However, Johnson et al fail to specifically disclose a

means to display a map of the predicted ablation of tissue for a given applied dosage, as well as means to display the actual ablation in comparison to the predicted model. Johnson et al also fail to disclose the particular position sensor means for generating signals to determine the position and orientation of the probe.

Rittman, III et al, as addressed previously, disclose an analogous RF system for treating tumors. In particular, the Rittman system includes the same basic RF probe, imaging and mapping system as set forth in the Johnson et al system. Rittman specifically teach that it is advantageous to provide predicted ablation mapping based on an applied dosage which can be compared to actual ablation images to predict and control the ablation of tissue (column 14).

Also addressed previously, Ben-Haim et al disclose the known use of position sensor coils to generate signals used to determine the position and orientation of a medical probe and/or catheter.

To have provided the Johnson et al system with a means to display a predicted ablation model to estimate the amount of tissue damage resultant from a given dosage would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Rittman, III et al. To have further provided the Johnson et al system with a position sensor means for determining the precise position and orientation of the probe during treatment would have been an obvious consideration for one of ordinary skill in the art.

***Response to Arguments***

Applicant's arguments filed November 29, 2006 have been fully considered but they are not persuasive.

Rittman discloses various imaging means for determining the position and location of the probe within the body. The location of the device is used to create a predicted ablation profile and to compare the actual ablation with the predicted ablation profile as addressed in this and the previous Office action. The examiner maintains that the use of any known positioning means to precisely determine the location of the device within the body, as is necessary for the device, would be an obvious design consideration for one of ordinary skill in the art. Ben-Haim et al teach that it is known to use a position sensor including coils as an alternative to ultrasonic and fluoroscopic imaging. This remains that examiner's combination, and the examiner maintains such a combination is properly motivated and without hindsight recognition.

Applicant asserts that Rittman discloses various electrode designs in order to reach specific target sites (page 9, last paragraph of the response), and that this is the solution for location of its various devices at a target site. Applicant continues to assert that Rittman is not at all concerned with accurate location based on position and orientation coordinates. While Rittman does disclose various electrode designs, this in no way indicates that Rittman is "not at all concerned with accurate location" of its various devices. Rittman clearly disclose the use of position and orientation coordinates of device for mapping the location of the probes in the body. The Abstract discloses the

use of imaging techniques used to map probe in the body, as does column 5, lines 42+ of the patent. Figures 6, 8 and 9 clearly show the use of the imaging display to show the location of the probe within the body, and column 13, line 33 through column 15, line 57 clearly discusses the use of the imaging to show not only the actual position of the electrode within the body, but also the proposed or predicted extent of ablation of tissue as well as the actual ablation of tissue. In particular, see col. 14, lines 20-64. The examiner maintains that Rittman expressly discloses the imaging of an ablation procedure, including showing predicted ablation patterns resultant from the measurement of local parameters such as temperature. Rittman fail to specifically disclose the use of position sensors for determining and displaying position and orientation coordinates. Rather, Rittman disclose numerous visualization alternatives including MRI, CT and ultrasound imaging.

Ben-Haim et al is cited merely for teaching an alternative imaging mechanism for a probe. In particular, Ben-Haim et al teach that it is known to use position sensors on a probe for providing imaging of a probe within the body. That Ben-Haim et al is not at all concerned with using the position and orientation coordinates of the probe for generating a map showing a predicted extent of ablation is immaterial to the rejection at hand. Rittman already uses position and orientation coordinates for such a purpose. Ben-Haim merely suggests another alternative means for deriving these position and orientation coordinates using sensing coils located in the probe. The examiner maintains that the use of an alternative imaging mechanism in a device (i.e. Rittman) that already discloses the use of several different imaging mechanisms is a properly



motivated suggestion for one of ordinary skill in the art. The examiner sees no need for a Declaration under 37 CFR 1.107(b) as suggested at page 11 of applicant's response since there is a very linear correlation in the examiner's suggestion of combining one known imaging mechanism (i.e. that of Ben-Haim et al) in a similar device that discloses the use of various types of imaging mechanisms.

Applicant's arguments with respect to the rejection involving the Johnson et al rejection are similarly not persuasive. Again, the Johnson et al reference teaches of detecting and treating tumors using a plurality of RF probes. Johnson et al specifically teach of using impedance measurements for monitoring the tumor and controlling treatment of the tumor. Rittman teaches of the use of imaging and predicted modeling techniques in a similar RF treatment system, and the examiner maintains that one of ordinary skill in the art would recognize that the use of the Rittman imaging and modeling control technique would be an obvious modification of the Johnson et al system. Further, Ben-Haim et al teach an alternative imaging mechanism whereby sensing coils are located on the probe for detection in a medical imaging system. The examiner is in no way using applicant's specification to modify the references. Rather, the prior art references are being modified to improve performance in their intended function with other relevant prior art teachings in analogous fields.

The examiner maintains that a *prima facie* case of obviousness has been duly met by showing objective teachings in the prior art used to modify a base reference and improve its performance. One of ordinary skill in the art would certainly recognize that alternative imaging techniques may be used with the Rittman system, particularly since

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Rittman disclose numerous different imaging techniques. As such, the examiner maintains that there is motivation for providing the teaching of the Ben-Haim et al imaging technique, which is used to locate a probe within the body, in the Rittman system. Similarly, the examiner maintains there is proper motivation for one of ordinary skill in the art to combine the imaging and predicted modeling system disclosed by Rittman with the Johnson et al system since both systems monitor and treat tumors using RF energy probes. For these reasons, the rejections are repeated.

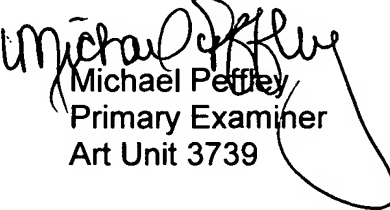
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michael Pettley  
Primary Examiner  
Art Unit 3739

.mp  
January 5, 2007